



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

IR-4 Waiver Determination Under the Pesticide Registration Improvement Act

Under the Pesticide Registration Improvement Act (PRIA), the Administrator shall waive the registration service fee for an application if the Administrator determines that—

1. The application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) as described in section 2 of Public Law 89-106 (7 U.S.C. 450i(e)); and
2. The waiver is in the public interest.

Often times, the IR-4 program submits the tolerance petition as required under the Federal Food, Drug, and Cosmetic Act (FFDCA), but the pesticide company (the registrant) submits the application to register the use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

While minor crops are typically high in value, typically there are insufficient financial resources within agrochemical companies to support the development of data to register pesticides for use on these crops. In addition, the potential profit from the minor crop use may not cover the cost of data development. Therefore, in 1963, Congress created the IR-4 Program, with the primary purpose to assist in obtaining pesticide registrations for minor crop growers. IR-4 receives the majority of its funding (currently approximately 90%) from the U.S. Department of Agriculture (USDA). The program operates in collaboration with USDA, the land grant university system, the agrochemical industry, commodity associations, and the U.S. Environmental Protection Agency. Since 1996, reduced-risk chemistries account for 80% of IR-4's research efforts.

IR-4 uses the following process to identify and prioritize its research:

1. Identification of Needs: Growers, commodity growers, and researchers (stakeholders) submit requests for specific pest management control needs.
2. Prioritization: On an annual basis, IR-4 convenes workshops with their stakeholders to discuss the research requests that have been submitted and to prioritize the most important needs. This assessment is based on the availability and efficacy of alternatives, pest damage potential, performance of the proposed project, and IPM compatibility.
3. Final Workplan: Based upon the input received from the annual workshop, IR-4 holds a national research planning meeting where the highest priority projects are selected for research. These decisions are made by IR-4 staff, as well as staff from EPA and USDA's Agricultural Research Service.

The factors used by IR-4 in prioritizing and funding research needs are consistent with the goals of the Food Quality Protection Act of 1996. FQPA defines minor uses to include crops grown on less than 300,000 acres where the use does not provide sufficient economic incentive to support registration and any one of the following factors is met:

1. There are insufficient efficacious alternative registered alternatives available for the use;
2. The alternatives to the pesticide use pose greater risks to the environment or public health;
3. The minor use pesticide plays or will play a significant part in managing pest resistance; or
4. The minor use pesticide plays or will play a significant part in an integrated pest management program.

The FQPA amendments to require the Agency to expedite the registration process for reduced-risk pesticides. FQPA defined reduced-risk pesticides to include those active ingredients that meet one or more of the following criteria:

1. Reduces the risks of pesticides to human health;
2. Reduces the risks of pesticides to nontarget organisms;
3. Reduces the potential for contamination of groundwater, surface water, or other valued environmental resources; or
4. Broadens the adoption of integrated pest management strategies, or makes such strategies more available or more effective.

In addition, the FQPA amendments lengthened the period of exclusive use of data generated in support of minor use registration. These factors all serve as a basis for determining that actions submitted by the IR-4 program are in the public interest.

PRIA also requires the Administrator to determine for IR-4 actions that waiving the registration service fee is in the public interest. One of the reasons for the creation of the IR-4 program was that the data development costs were considered to be a deterrent for pesticide companies to support minor use registrations. The registration service fee required by PRIA could also be a deterrent to the pursuit of minor use registrations. The cost of developing data for many registrations is approximately \$100,000 per use.

Moreover, when the Agency had the authority to collect tolerance petition fees, EPA traditionally waived these fees for tolerance petitions submitted by the IR-4 program. The imposition of registration service fees for IR-4 supported actions could be an additional disincentive for companies to seek registration for uses supported by IR-4 data. The result would be the expenditure of federal funds to support registrations without growers gaining access to these products. IR-4's investment in developing data in support of registration for lower toxicity compounds is consistent with the Agency's desire to register alternatives for higher risk compounds.

In addition, the intent of the FQPA amendments relative to minor uses was to promote the registration of pesticides for minor uses. The Agency was encouraged to develop incentives for registrants to pursue minor use registrations. Subsequently, both the Tolerance Reassessment Advisory Committee (TRAC) and the Committee to Advise on Reassessment and Transition (CARAT) advised the Agency to develop incentives to promote the registration of minor use pesticides. A high percentage of the minor use registrations issued each year by the Agency are the direct result of data generation by the IR-4 program. Waiving of the registration service fee for registration actions associated with tolerance petitions submitted by IR-4 would serve as a significant incentive for registrants to pursue registration of minor uses supported by the IR-4 program's data generation activities.

Historically, the registration application to add an IR-4 supported use to a label has not been submitted simultaneously with the IR-4 tolerance petition. Often times, the label request has arrived several months to years after the IR-4 tolerance petition has been submitted to the Agency. This delay in the label submission ultimately affects the Agency's ability to act on the tolerance petition submitted by IR-4 in a timely manner.

Under PRIA, however, only applications that are solely associated with a tolerance petition submitted by IR-4 are eligible for a waiver of the registration service fee. The Agency believes that "solely associated" means simultaneous submission of the IR-4 petition and the registrant's label request. Therefore, only applications submitted with the IR-4 petition will be eligible for an IR-4 waiver of the registration service fee. Applications that are otherwise associated with an IR-4 petition but have not been submitted with the IR-4 petition may, if appropriate, nonetheless request a minor use or small business waiver.

Waiver Determination:

Therefore, the Office of Pesticide Programs has determined that waiving registration service fees under the Pesticide Registration Improvement Act for registration applications submitted solely in connection with IR-4 tolerance petitions is in the public interest. When such applications are submitted to the Agency, OPP will screen the incoming application to determine that the application is solely associated with a tolerance petition submitted by the IR-4 program. Once OPP makes that determination, it will issue a waiver for the otherwise required registration service fee. To be eligible for the IR-4 waiver, the registration request must be submitted simultaneously with the IR-4 tolerance petition. Accordingly, delays in the submission of the registration request will result in a determination that the registration action is not solely associated with a tolerance petition submitted by IR-4 and, therefore, is not eligible for the IR-4 waiver under PRIA.

James J. Jones, Director
Office of Pesticide Programs